Instrumentation Industries, Inc.
We make Respiratory Care Work!

SEP 1 1 2008

K081693

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Revised: August 7, 2008
Contact Person for this Submission: Doris F. Walter
Submitter: Doris F. Walter
Official Correspondent for Instrumentation Industries, Inc.: Edward C. Horey

510(k) SUMMARY
For
NS Series NIF Meters

Trade Name	NS Series NIF (Negative Inspiratory Force) Meters
Common Name	NIF Meter
Classification Name	Inspiratory Airway Pressure Meter
Regulation	21 CFR 868.1780
Predicate Devices	1. Instrumentation Industries, Inc. – BE 149 – Preamendment device 2. Smiths Medical – NIF Kit
Device Description	The NS Series NIF Meters are intended to measure inspiratory airway pressures of up to 30, 60 or 120 cm H_20, dependent upon the specific model used.
Intended Use of the Device NS 30-PBR NS 60-PBR NS 60-TRR NS 30-TRR NS 60-TBR NS 120-TRR	The Instrumentation Industries, Inc. Negative Inspiratory Force (NIF) Meters are devices used to measure and monitor patient inspiratory effort. During use the NIF Meter is attached to the patient airway at a point that provides optimal readings of patient respiratory effort. Federal law restricts these devices to sale by or on the order of a physician.
Technological Characteristics	**Similarities:** 1. The function of the NS Series NIF Meters, the BE 149 and the Smiths Medical NIF kit are the same. All are analog-faced manometers used to measure inspiratory pressure.

	2. The anticipated usage of all of the devices is the same. All versions of the NS NIF meters, the BE 149 and the Smiths Medical NIF Kit include a memory indicator pointer (MIP) that records the maximum pressure reached during inspiration. The pointer can be re-set and the exercise repeated. 3. The operation of the NIF meters is technologically the same: All have a diaphragm which, when exposed to a patient's inhaled breath, activates the pressure and MIP via a spring. **Differences:** 1. The capacity varies among them: The BE 149 range = 0-60 cm H_20 The Smiths Medical NIF Kit range = 0-60 cm H_20 The NS Series offers three pressure ranges: 0-30, 0-60, 0-120 cm H_20 2. The Smiths Medical NIF meter is sold in an inclusive kit; The NS Series NIF meters are sold alone; adapters and tubing are not included. 3. The Smiths Medical NIF meter is offered with only one type of attachment point which is a small-bore tubing port. The III NIF meters have three: ¼" NPT bottom fitting, ¼" NPT rear fitting, and a small-bore tubing fitting.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

SEP 1 1 2008

Ms. Doris F. Walter
Regulatory Affairs/Quality Assurance Manager
Instrumentation Industries, Incorporated
2990 Industrial Boulevard
Bethel Park, Pennsylvania 15102-2536

Re: K081693
Trade/Device Name: NS Series NIF (Negative Inspiratory Force) Meters
Regulation Number: 21 CFR 868.1780
Regulation Name: Inspiratory Airway Pressure Meter
Regulatory Class: II
Product Code: BXR
Dated: September 3, 2008
Received: September 4, 2008

Dear Ms. Walter:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050. This letter will allow you to begin marketing your device as described in your Section 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Center for Devices and Radiological Health's (CDRH's) Office of Compliance at (240) 276-0115. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). For questions regarding postmarket surveillance, please contact CDRH's Office of Surveillance and Biometric's (OSB's) Division of Postmarket Surveillance at 240-276-3474. For questions regarding the reporting of device adverse events (Medical Device Reporting (MDR)), please contact the Division of Surveillance Systems at 240-276-3464. You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (240) 276-3150 or at its Internet address http://www.fda.gov/cdrh/industry/support/index.html.

Sincerely yours,

Chiu Lin, Ph.D.
Director
Division of Anesthesiology, General Hospital,
Infection Control and Dental Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

Indications for Use

510(k) Number (if known):

K081693

Device Name: NS series NIF (Negative Inspiratory Force) Meters

Statement of Indications for Use:

The Instrumentation Industries, Inc. Negative Inspiratory Force (NIF) Meters are devices used to measure and monitor patient inspiratory effort. During use the NIF Meter is attached to the patient airway at a point that provides optimal readings of patient respiratory effort.

Federal law restricts these devices to sale by or on the order of a physician.

Prescription Use ___√___ (Part 21 CFR 801 Subpart D) And/Or Over-The-Counter Use _____ (21 CFR 801 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE – CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

(Division Sign-Off)
Division of Anesthesiology, General Hospital Infection Control, Dental Devices

510(k) Number: K081693